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EXAMINER

NOGUEKOLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Handwritten initials

Office Action Summary

Application No.

09/961,249

Applicant(s)

HASHIMOTO ET AL.

Examiner

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) _____ is/are pending in the application.
4a) Of the above claim(s) 1 and 3-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9,10,13,14,16,17,19-22,24,25,27,33 and 38-40 is/are rejected.
- 7) ☒ Claim(s) 8,11,12,15, 18, 23, 26, 28-32, 34-37, and 41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 02182004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Response to Amendment

1. Applicant's amendment of February 18, 2004 does not render the application allowable.

Response to Arguments

2. Applicant's arguments filed February 18, 2004 have been fully considered but they are not persuasive.

With respect to the rejection of claim 1 as being anticipated under 35 U.S.C. §102 by Hashimoto alleges, "Paragraph [0058] of the '183 publication (as well as the description of notations) discloses that elements 104, 105, and 106 are conductors, not electrodes" (page 13 of the amendment). This position misinterprets the disclosure of the '183 publication. At the outset, it can be clearly seen from the abstract that Hashimoto discloses a sensor having electrodes: "The detection of the target nucleic acid is carried out by hybridizing the first nucleic acid immobilized on the **electrode** 10 with the second complementary nucleic acid on the electrode in preset conditions, applying a **voltage** to the first nucleic acid immobilized on the **electrode** and subsequently measuring the signal generated by the application [emphasis added]." Paragraph [0058] states, "Drawing 9 and the fundamental structure of the electrode in the sensor of drawing 10 can use the electrode of a publication for drawing 1 ..." It would be clear to one with ordinary skill in the art from the context of paragraph [0058] that by "conductor" Hashimoto means an electrical conductor of a probe or sensor, that is, an electrode.

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Indeed, paragraph [0059], which immediately follows paragraph [0058], describes drawings 12-15 as showing different embodiments of a sensor having a pair of opposing electrodes with associated circuitry including a power source and meter.

With respect to the rejection of claim 1 as being anticipated under 35 U.S.C. 102 § by Miyahara Applicant alleges that Miyahara does not disclose a counter electrode arranged opposite to the nucleic acid chain fixed electrodes, but instead a counter electrode arranged to one side of the nucleic acid chain fixed electrodes. Applicant is construing the definition of "opposite" too narrowly. According to Webster's II New Riverside University Dictionary, 1994 Houghton Mifflin Company, "opposite" means, as an adjective, "[l]ocated or placed directly across from something else or from each other <opposite ends of a street>", as an adverb, "in an opposite position or positions <standing opposite in the courtroom>, and as a preposition, "[a]cross from or facing <a hotel opposite the park>." Just because in Figure 4 the counter electrode is on the same substrate (plane) as the nucleic acid electrodes does not mean that they are not opposite one another. Applicant should also note the configuration shown in Figure 2 could also be construed as showing a counter electrode opposite the nucleic acid electrodes.

With respect to the rejection of claim 16 as being anticipated under 35 U.S.C. 102 § by Miyahara. Applicant alleges that Miyahara does not disclose a plurality of switching elements to turn off and on a connection between the plurality of nucleic acid chain fixed electrodes and the plurality of signal lines. Applicant has overlooked Figure 4(c), which shows scanning means for selecting individual nucleic acid chain fixed electrodes.

Consequently, in light of the above discussion various claims are still unpatentable over the cited prior art.

Status of the Objections and Rejections Applied in the Office Action of November 18, 2003

3. All of the objections are withdrawn.
4. The rejection of claims 7, 14, and 20 under 35 U.S.C. § 112, first paragraph, is withdrawn.
5. The rejection of claims 2, 6, 7, 10-15, 19, and 20 under 35 U.S.C. § 112, second paragraph, is withdrawn.
6. The double patenting rejections against claims 1, 3, 6, 9, 10, and 13 are withdrawn.
7. The rejection of claims 1, 4, 5-7 as being anticipated by Hashimoto under 35 U.S.C. § 102 (b) is maintained.
8. The rejection of claims 2, 3, and 9 as being anticipated by Hashimoto under 35 U.S.C. § 102 (b) is withdrawn.
9. The rejection of claims 1, 5, 7 as being anticipated by Miyahara under 35 U.S.C. § 102 (a) is maintained.

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10. The rejection of claims 2, 3, 16, and 19 as being anticipated by Miyahara under 35 U.S.C. § 102 (a) is withdrawn.

Claim Rejections - 35 USC § 112

11. Claims 13, 14, 39, and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claims 13 and 14: the statutory class of invention is not clear. Claim 10 is directed to a nucleic acid detection sensor. However, claims 13 and 14 only further limit claim 10 by providing method of use steps or desired results;

b) Claim 39 recites the limitation "the reference electrode" in line 1. There is insufficient antecedent basis for this limitation in the claim; and

c) Claim 40, line 2: should the first occurrence of "the" be -- a --, the second occurrence of "the", and "electrodes," be -- electrode, --?

Claim Rejections - 35 USC § 102

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

13. Claims 1 and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by the JPO computer translation of Hashimoto et al. (JP 10-146183), hereafter "Hashimoto".

Addressing claim 1, Hashimoto teaches a nucleic acid detection sensor comprising

a plurality of nucleic acid chain fixed electrodes to which a probe nucleic acid chain is fixed (electrodes 105 and 106 in Drawings 10(a) and 10(b)); and

a counter electrode which is arranged opposite to the nucleic acid chain fixed electrode (electrode 104 in Drawings 10(a) and 10(b)), wherein a current flows between the counter electrode and each nucleic acid chain fixed electrode when a voltage is applied between the nucleic acid fixed electrodes and the counter electrode (paragraph [0059] of *Detailed Description*).

Addressing claim 4, as seen in Drawings 10(a) and 10(b) the counter electrode and the nucleic acid chain fixed electrodes have flat planes as claimed.

Addressing claim 5, as seen in Drawings 10(a) and 10(b) a test liquid can flow between the counter electrode and the nucleic acid chain fixed electrodes.

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Addressing claim 6, exposing the detection sensor of apparatus to a test liquid is discussed in paragraphs [0087]-[0092] of the *Detailed Description*, for example.

Addressing claim 7, as seen in drawings 15 and 16 embodiments are disclosed where test liquid flows between the counter electrode and the nucleic acid chain fixed electrode. Note the ammeter in drawings 12-14.

14. Claims 1 and 5-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Miyahara et al. (EP 1120646 A1), hereafter "Miyahara".

Addressing claim 1, Miyahara teaches a nucleic acid detection sensor comprising

a plurality of nucleic acid chain fixed electrodes to which a probe nucleic acid chain is fixed (electrodes 8 in Figure 2); and

a counter electrode which is arranged opposite to the nucleic acid chain fixed electrode (electrode 16 in Figure 2), wherein a current flows between the counter electrode and each nucleic acid chain fixed electrode when a voltage is applied between the nucleic acid fixed electrodes and the counter electrode (paragraph [0035]).

Addressing claim 5, as seen in Figure 2 a test liquid can flow between the counter electrode and the nucleic acid chain fixed electrodes.

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Addressing claim 6, exposing the detection sensor of apparatus to a test liquid is discussed in paragraphs [0031]-[0046].

Addressing claim 7, in the embodiments shown in Figures 4(a)-(c) the test liquid must cover both the nucleic acid chain fixed electrodes and the corner electrode in order for a measurement to be taken. In the embodiment of Figure 2 as inferred from Figure 3 test liquid is introduced between the nucleic acid chain fixed electrodes and the counter electrode

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 3, 9, 10, 13, 14, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over the JPO computer translation of Hashimoto et al. (JP 10-146183), hereafter "Hashimoto".

Addressing claim 3, Hashimoto teaches a nucleic acid detection sensor comprising

a plurality of nucleic acid chain fixed electrodes to which a probe nucleic acid chain is fixed (electrodes 105 and 106 in Drawings 10(a) and 10(b)); and

a counter electrode which is arranged opposite to the nucleic acid chain fixed electrode (electrode 104 in Drawings 10(a) and 10(b)), wherein a current flows between the counter electrode and each nucleic acid chain fixed electrode when a voltage is applied between the nucleic acid fixed electrodes and the counter electrode (paragraph [0059] of *Detailed Description*).

Hashimoto does not mention a plurality of counter electrodes for the nucleic acid chain fixed electrodes, respectively. However, barring evidence to the contrary, this is mere multiplication of parts to duplicate effect. It would have been obvious to one with ordinary skill in the art at the time the invention was made provide to a plurality of counter electrodes so that

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different measurements could be performed. For example, different electric fields could be applied across the various pairs of nucleic acid chain fixed electrodes and counter electrodes. If just one counter electrode was used there is a likelihood that the different electric fields would interfere with one another and adversely affect the measurements.

Addressing claim 9, Hashimoto teaches a nucleic acid detection sensor comprising

a plurality of nucleic acid chain fixed electrodes to which a probe nucleic acid chain is fixed (electrodes 105 and 106 in Drawings 10(a) and 10(b)); and

a counter electrode which is arranged opposite to the nucleic acid chain fixed electrode (electrode 104 in Drawings 10(a) and 10(b)), wherein a current flows between the counter electrode and each nucleic acid chain fixed electrode when a voltage is applied between the nucleic acid fixed electrodes and the counter electrode (paragraph [0059] of *Detailed Description*).

Hashimoto does not mention a plurality of reference electrodes for the nucleic acid chain fixed electrodes, respectively. Although it should be noted that Hashimoto does teach providing a reference electrode in conjunction with a nucleic acid chain fixed electrode and a counter electrode (paragraph [0013] of the *Detailed Description*). Barring evidence to the contrary, providing multiple electrodes is mere multiplication of parts to duplicate effect. It would have been obvious to one with ordinary skill in the art at the time the invention was made provide to a plurality of reference electrodes so that different measurements could be performed.

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For example, different electric fields could be applied across the various pairs of nucleic acid chain fixed electrodes and counter electrodes. If just one reference electrode was used there is a likelihood that the different electric fields would interfere with one another and adversely affect the measurements.

Addressing claim 10, Hashimoto teaches a nucleic acid detection sensor comprising a plurality of nucleic acid chain fixed electrodes to which a probe nucleic acid chain is fixed (electrodes 105 and 106 in Drawings 10(a) and 10(b)); and a counter electrode which is arranged opposite to the nucleic acid chain fixed electrode (electrode 104 in Drawings 10(a) and 10(b)), wherein a current flows between the counter electrode and each nucleic acid chain fixed electrode when a voltage is applied between the nucleic acid fixed electrodes and the counter electrode (paragraph [0059] of *Detailed Description*).

Hashimoto does not mention a plurality of reference electrodes for the nucleic acid chain fixed electrodes, respectively. Although it should be noted that Hashimoto does teach providing a reference electrode in conjunction with a nucleic acid chain fixed electrode and a counter electrode (paragraph [0013] of the *Detailed Description*). Barring evidence to the contrary, providing multiple electrodes is mere multiplication of parts to duplicate effect. It would have been obvious to one with ordinary skill in the art at the time the invention was made provide to a plurality of reference electrodes so that different measurements could be performed. For example, different electric fields could be applied across the various pairs of nucleic acid

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chain fixed electrodes and counter electrodes. If just one reference electrode was used there is a likelihood that the different electric fields would interfere with one another and adversely affect the measurements.

Addressing claim 13, exposing the detection sensor of apparatus to a test liquid is discussed in paragraphs [0031]-[0046].

Addressing claim 14, as seen in drawings 15 and 16 embodiments are disclosed where test liquid flows between the counter electrode and the nucleic acid chain fixed electrode. Note the ammeter in drawings 12-14.

Addressing claim 38, as with the reference electrodes in claim 10 providing a plurality of counter electrodes is just mere multiplication of parts to duplicate effect. By providing a counter electrode and reference electrode for each nucleic acid chain fixed electrode a plurality of electrically independent three-electrode measurement cells will be created. This will allow different electrical fields to be applied and will avoid interference that may arise from using common electrodes.

19. Claims 3, 16, 22, 24, 25, 27, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyahara et al. (EP 1120646 A1), hereafter "Miyahara".

Addressing claims 3 and 40, Miyahara teaches a nucleic acid detection sensor comprising

a plurality of nucleic acid chain fixed electrodes to which a probe nucleic acid chain is fixed (electrodes 8 in Figure 2); and

a counter electrode which is arranged opposite to the nucleic acid chain fixed electrode (electrode 16 in Figure 2), wherein a current flows between the counter electrode and each nucleic acid chain fixed electrode when a voltage is applied between the nucleic acid fixed electrodes and the counter electrode (paragraph [0035]).

Miyahara does not mention a plurality of counter electrodes for the nucleic acid chain fixed electrodes, respectively. However, barring evidence to the contrary, this is mere multiplication of parts to duplicate effect. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide to a plurality of counter electrodes so that different measurements could be performed. For example, different electric fields could be simultaneously applied across the various pairs of nucleic acid chain fixed electrodes and counter electrodes. In the embodiment shown in Figure 4(c) different electric fields could be applied to the nucleic acid chain fixed electrodes; however, they could only be applied separately, in sequence. With multiple counter electrodes different fields could be applied to the different nucleic acid chain fixed electrodes simultaneously.

For claim 40, note that the examiner assumed that Applicant intends for a counter electrode to be provided for each nucleic acid chain fixed electrode.

Addressing claim 16, Miyahara teaches a nucleic acid detection sensor comprising

a plurality of nucleic acid chain fixed electrodes to each of which a probe nucleic acid chain is fixed (electrodes 8 in Figure 2);

a counter electrode (electrode 16 in Figure 2);

a scanning line configured to transmit select signals for selecting a plurality of nucleic acid chain fixed electrodes one by one (scanning terminal 27 in Figure 4(c) must receive a selector signal. See paragraph [0036]);

a plurality of signal lines configured to transmit a measurement signal from the plurality of nucleic acid chain fixed electrodes (leads 13 in Figure 4(c));

and

a switching element connected with the plurality of nucleic acid chain fixed electrodes, the plurality of scanning lines, and the signal line, configured to turn on and turn off a connection between the plurality of nucleic acid chain fixed electrodes and plurality of the signal lines according to the select signal from the scanning line, and provided for the nucleic acid chain fixed electrode, respectively.

Miyahara does not mention a plurality of scanning lines and a plurality of selector switches; however, barring evidence to the contrary these features are mere duplication of parts to duplicate effect. The selector switch can select from only a limited number of nucleic acid chain fixed electrodes. Thus, for a large plurality of nucleic acid chain fixed electrodes several selector switches and associated scanning lines would be needed. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide as many selector switches and scanning lines as needed to access all of the nucleic acid chain fixed electrodes.

Addressing claim 22, since Miyahara teaches automatically selecting individual nucleic acid chain fixed electrodes (paragraph [0036]), it would have been obvious to one with ordinary skill in the art at the time the invention was made provide to provide means for selecting the nucleic acid chain fixed electrodes.

Addressing claim 24, Miyahara teaches an A-D converter (paragraph [36]). Barring evidence to the contrary, providing multiple A-D converters is mere multiplication of parts to duplicate effect. It would have been obvious to one with ordinary skill in the art at the time the invention was made provide to provide a plurality of A-D converters to accommodate a plurality of signal lines.

Addressing claims 25 and 27, these claims require a plurality of amplifiers. It was known in the art at the time of the invention to boost the measurement signal for further processing, such as display or software analysis by a computer (which is disclosed by Miyahara). As for a plurality of amplifiers, it would have been obvious to provide as many amplifiers as needed for the plurality of signal lines.

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20. Claims 17 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyahara as applied to claims 3 and 16 above, and further in view of Hashimoto et al.

(JP 10-146183), hereafter "Hashimoto".

Addressing claim 17, Miyahara does not mention a plurality of reference electrodes for the nucleic acid chain fixed electrodes.

Hashimoto teaches a nucleic acid detection sensor comprising

a plurality of nucleic acid chain fixed electrodes to which a probe nucleic acid chain is fixed (electrodes 105 and 106 in Drawings 10(a) and 10(b)); and

a counter electrode which is arranged opposite to the nucleic acid chain fixed electrode (electrode 104 in Drawings 10(a) and 10(b)), wherein a current flows between the counter electrode and each nucleic acid chain fixed electrode when a voltage is applied between the nucleic acid fixed electrodes and the counter electrode (paragraph [0059] of *Detailed Description*).

Hashimoto also teaches providing a reference electrode in conjunction with a nucleic acid chain fixed electrode and a counter electrode (paragraph [0013] of the *Detailed Description*).

It would have been obvious to one with ordinary skill in the art at the time the invention was made provide to a reference electrode for a nucleic acid chain electrode as taught by Hashimoto in the invention of Miyahara because as was known in the art using a separate counter and reference electrodes will improve the accuracy of some types of measurements, particularly current measurement, because current will largely flow through the counter electrode and thus the reference electrode will truly be a reference and have a fixed potential.

Barring evidence to the contrary, providing multiple electrodes is mere multiplication of parts to duplicate effect. It would have been obvious to one with ordinary skill in the art at the time the invention was made provide to a plurality of reference electrodes so that different measurements could be performed. For example, different electric fields could be applied across the various pairs of nucleic acid chain fixed electrodes and counter electrodes. If just one reference electrode was used there is a likelihood that the different electric fields would interfere with one another and adversely affect the measurements.

Addressing claim 19, exposing the detection sensor of apparatus to a test liquid is discussed in paragraphs [0031]-[0046].

Addressing claim 20, in the embodiments shown in Figures 4(a)-(c) the test liquid must cover both the nucleic acid chain fixed electrodes and the corner electrode in order for a measurement to be taken. In the embodiment of Figure 2 as inferred from Figure 3 test liquid is introduced between the nucleic acid chain fixed electrodes and the counter electrode

Addressing claim 21, Miyahara does not mention a plurality of reference electrodes for the nucleic acid chain fixed electrodes.

Hashimoto teaches a nucleic acid detection sensor comprising

a plurality of nucleic acid chain fixed electrodes to which a probe nucleic acid chain is fixed (electrodes 105 and 106 in Drawings 10(a) and 10(b)); and

a counter electrode which is arranged opposite to the nucleic acid chain fixed electrode (electrode 104 in Drawings 10(a) and 10(b)), wherein a current flows between the counter electrode and each nucleic acid chain fixed electrode when a voltage is applied between the nucleic acid fixed electrodes and the counter electrode (paragraph [0059] of *Detailed Description*).

Hashimoto also teaches providing a reference electrode in conjunction with a nucleic acid chain fixed electrode and a counter electrode (paragraph [0013] of the *Detailed Description*).

It would have been obvious to one with ordinary skill in the art at the time the invention was made provide to a reference electrode for a nucleic acid chain electrode as taught by Hashimoto in the invention of Miyahara because as was known in the art using a separate counter and reference electrodes will improve the accuracy of some types of measurements, particularly current measurement, because current will largely flow through the counter electrode and thus the reference electrode will truly be a reference and have a fixed potential.

21. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miyahara et al. (EP 1120646 A1), hereafter "Miyahara," in view of Hashimoto et al. (JP 10-146183), hereafter "Hashimoto."

Miyahara teaches a nucleic acid detection sensor comprising

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a plurality of nucleic acid chain fixed electrodes to which a probe nucleic acid chain is fixed (electrodes 8 in Figure 2); and

a counter electrode which is arranged opposite to the nucleic acid chain fixed electrode (electrode 16 in Figure 2), wherein a current flows between the counter electrode and each nucleic acid chain fixed electrode when a voltage is applied between the nucleic acid fixed electrodes and the counter electrode (paragraph [0035]).

Hashimoto teaches a nucleic acid detection sensor comprising

a plurality of nucleic acid chain fixed electrodes to which a probe nucleic acid chain is fixed (electrodes 105 and 106 in Drawings 10(a) and 10(b)); and

a counter electrode which is arranged opposite to the nucleic acid chain fixed electrode (electrode 104 in Drawings 10(a) and 10(b)), wherein a current flows between the counter electrode and each nucleic acid chain fixed electrode when a voltage is applied between the nucleic acid fixed electrodes and the counter electrode (paragraph [0059] of *Detailed Description*).

Hashimoto also teaches providing a reference electrode in conjunction with a nucleic acid chain fixed electrode and a counter electrode (paragraph [0013] of the *Detailed Description*).

It would have been obvious to one with ordinary skill in the art at the time the invention was made provide to a reference electrode for a nucleic acid chain electrode as taught by Hashimoto in the invention of Miyahara because as was known in the art using a separate counter and reference electrodes will improve the accuracy of some types of measurements, particularly current measurement, because current will largely flow through the counter electrode and thus the reference electrode will truly be a reference and have a fixed potential.

Allowable Subject Matter

22. Claims 8, 11, 12, 18, 23, 26, 28-32, 34-37, and 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

23. Claim 39 would be allowable if rewritten to overcome the rejection under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

24. The following is a statement of reasons for the indication of allowable subject matter:

a) the allowability Claim 8 has been addressed in the Office action of November 18, 2003;

b) Claims 11 and 29 require the nucleic acid chain fixed electrodes to be comb electrodes.

See the reasons for allowability of claim 8,

- c) Claim 12 requires “a reference resistor connected between an output side of the first amplifier and the reference potential.” Hashimoto only discloses a variable resistor in parallel with a power source (drawing 14). The schematic in Figure 4(c) of Miyahara does not show any amplifiers or resistors;
- d) Claims 15, 18, and 35 requires the counter electrode to surround the nucleic acid chain fixed electrodes. In Hashimoto the counter electrode and the nucleic acid chain fixed electrodes are on opposing facing substrates and thus on different planes (drawings 10-15). In Miyahara the counter electrode is either on the same plane as the nucleic acid chain fixed electrodes, but arranged to one side of the nucleic acid chain fixed electrodes (Figure 4), or the counter electrode is on a different plane (Figure 2);
- e) Claim 23 requires a timing pulse generator and a counter for use in generating the select signals. Miyahara does not provide details on the scanning terminal;
- f) Claim 26 requires a plurality of transistors connected to the plurality of signal lines. The schematic in Figure 4(c) of Miyahara does not show or suggest any transistors connected to the plurality of signal lines;
- g) Claim 28 requires the plurality of signal lines to be covered with insulation films. In Miyahara the plurality of signal lines are already covered in part by the cover (4);

- h) Claim 30 requires the nucleic acid chain fixed electrodes and reference electrodes to be mutually engaged comb electrodes. See the reasons for allowability of claim 8;
- i) Claim 31 depends from allowable claim 29;
- j) Claim 32 requires the counter electrode to be a comb electrode. See the reasons for allowability of claim 8,
- k) Claims 34 and 36 require the nucleic acid chain fixed electrodes and reference electrode to be mutually engaged comb electrodes. See the reasons for allowability of claim 8;
- l) Claim 37 requires the nucleic acid chain fixed electrodes and counter electrode to be mutually engaged comb electrodes. See the reasons for allowability of claim 8; and
- m) Claims 39 and 41 require the reference electrode to surround the nucleic acid chain fixed electrodes. In Hashimoto the counter electrode and the nucleic acid chain fixed electrodes are on opposing facing substrates and thus on different planes (drawings 10-15). In Miyahara the counter electrode is either on the same plane as the nucleic acid chain fixed electrodes, but arranged to one side of the nucleic acid chain fixed electrodes (Figure 4), or the counter electrode is on a different plane (Figure 2).

Final Rejection

25. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Noguerola
Primary Examiner
AU 1753
May 4, 2004